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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,743	02/16/2001	Yuichi Murayama	P689a	5528

7590 09/29/2003

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EXAMINER
ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,743	MURAYAMA ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The "Prior Art" portions of Figures 1-5F should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Given the claim language, it is not clear as to what is meant by "coil compaction." There has been no prior recitation requiring coils. Any art rejection is as best understood.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7-8, 11-16, 18-19, and 22-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Roth et al. in US Patent No. 5,879,713.

Regarding claim 1, Roth et al. disclose an endovascular apparatus for developing an inflammatory response in a body cavity with cellular manipulation having:

- A separable implant (such as a coating on a tubular biological structure (whether natural or artificially formed), as recited in column 13, lines 5-15, a microparticle, etc.) made at least in part of at least one biocompatible and bioabsorbable polymer, as recited in column 3, lines 30-67 and columns 4-6
- An endovascular placement device associated with the separable implant adapted to dispose the implant into the body cavity (such as those inherent for placement of stents as well as that recited in column 11, lines 4-12 and columns 13 and 14 for delivery of microparticles).

Regarding claim 2, Roth et al. disclose an implant that further is at least in part of a noncollagenous protein, as recited in column 3, lines 62-67 and column 4, lines 1-30.

Regarding claim 3, Roth et al. disclose an implant that further is at least in part of a growth factor, as recited in column 10, lines 1-30.

Regarding claim 4, Roth et al. disclose an implant that further is at least in part of a one selected from the group of VEGF, b-FGF, TGF, PDGF or mixtures thereof, as recited in column 10, lines 1-30.

Regarding claim 5, Roth et al. disclose an implant that further is at least in part of a basic fibroblast growth factor, as recited in column 10, lines 22-25.

Regarding claim 7, Roth et al. disclose a biocompatible and bioabsorbable polymer that is at least one polymer selected from the group consisting of polyglycolic acid, poly.about.glycolic acid/**poly-L-lactic acid copolymers**, polycaprolactive, polyhydroxybutyrate/hydroxyvalerate copolymers, poly-L-lactide, polydioxanone, **polycarbonates**, and polyanhydrides, as recited in column 4, lines 1-30 and column 6, lines 35-45.

Regarding claim 8, Roth et al. disclose a biocompatible and bioabsorbable protein that is at least one protein selected from the group consisting of fibrinogen, fibronectin, vitronectin, laminin, and gelatin, as recited in column 3, lines 61-67.

Regarding claim 11, Roth et al. disclose a biocompatible and bioabsorbable polymer that promotes cellular manipulation, controlled inflammatory response and vascular healing, as recited in column 3, lines 30-40 for example.

Regarding claims 12-16 and 18-19, see above rejection for the method claims correspond to the apparatus claims as rejected.

Regarding claim 22, Roth et al. disclose a biocompatible and bioabsorbable polymer that does not elicit intense chronic foreign body reaction, as recited in column 3, lines 30-40 for example.

Regarding claim 23, Roth et al. disclose the endovascular placement device is used to dispose the implant at an implantation site and where the biocompatible and bioabsorbable polymer is gradually absorbed and does not leave residua in the implantation site, as discussed in columns 13 and 14.

Regarding claim 24, Roth et al. disclose a biocompatible and bioabsorbable polymer that is faster degrading and provides a stronger inflammatory reaction than metal coils (although the analogy to metal coils is not explicitly recited, given the structure would necessarily accomplish that as claimed – further degradation rates for metal coils has not been included in that claimed).

Regarding claim 25, Roth et al. disclose a biocompatible and bioabsorbable polymer that has a selected composition to provide a controlled degradation time to thereby control intravascular inflammatory reactions, as recited in column 13.

Regarding claim 26, Roth et al. disclose a biocompatible and bioabsorbable polymer that regenerates tissue through the interaction of immunologic cells (although not explicitly stated, given that disclosed would accomplish that claimed).

Regarding claim 27, Roth et al. disclose a biocompatible and bioabsorbable polymer that stimulates cellular infiltration and proliferation in the process of degradation to accelerate fibrosis (although not explicitly stated, given that disclosed would accomplish that claimed).

Regarding claim 28, Roth et al. disclose a biocompatible and bioabsorbable polymer that accelerates fibrosis within an aneurysm to more strongly anchor the implant than does metal coils, as recited in column 14, lines 5-25. Again, given the broad nature of what can encompass metal coils, Roth et al. accomplish that claimed.

Regarding claim 29, Roth et al. disclose a biocompatible and bioabsorbable polymer is characterized by generating more connective tissue and a less unorganized clot than metal coils so that an aneurysm in which the implant is disposed is more resistant to a water hammer effect of pulsatile blood than when treated by metal coils. Again, given the broad nature of what can encompass metal coils, Roth et al. accomplish that claimed. Further, given the structure as disclosed by Roth et al. would necessarily achieve that claimed.

Regarding claim 30, Roth et al. disclose a biocompatible and bioabsorbable polymer that restricts coil compaction by accelerated scar formation.

Regarding claim 31, Roth et al. disclose a biocompatible and bioabsorbable polymer that restricts aneurysm recanalization by accelerated scar formation (although not explicitly recited, in inherent in the structure).

Regarding claim 32, Roth et al. disclose a biocompatible and bioabsorbable polymer that induces organized connective tissue to fill an aneurysm and to retract the aneurysm over time due to maturation of collagen fibers to reduce aneurysm size and decrease aneurysm compression on brain parenchyma or cranial nerves (although not explicitly recited, in inherent in the structure).

Regarding claim 33, Roth et al. disclose a biocompatible and bioabsorbable polymer that is less thrombogenic than metal coils and accelerates aneurysm healing with less thrombogenicity. Again, given the broad nature of what can encompass metal coils, Roth et al. accomplish that claimed. Further, given the structure as disclosed by Roth et al. would necessarily achieve that claimed.

Applicant is reminded that functional language does not carry patentable weight in apparatus claims. Statements that do no define any structure accordingly do not serve to distinguish.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 6, 9-10, 17, 20-21, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et al. in US Patent No. 5,879,713.

Roth et al. disclose the invention with the exception of:

- An implant that further is at least in part of a mixture of the vascular endothelial growth factor and a basic fibroblast growth factor.
- A radio-opaque material is disposed on the implant.
- An implant composed of a radio-opaque material, and wherein the biocompatible and bioabsorbable polymer or protein is disposed thereon.

On the other hand, it would be obvious to one with ordinary skill in the art to provide mixture of the vascular endothelial growth factor and a basic fibroblast growth factor for the purpose of promoting proper healing. Further the specification for the current application does not provide any criticality to the mixture, rather just states that it is preferred.

Further, radio-opaque material is well known in the art and it would be obvious to provide radio-opaque material on the implant where the implant is composed of a radio-opaque material, and wherein the biocompatible and bioabsorbable polymer or protein is disposed thereon for the purpose of proper placement and tracking.

Additionally, a biocompatible and bioabsorbable polymer that is a mixture of polyglycolic/poly-L-lactic acid copolymers with a 90/10 molar ratio of glycolic to L-lactic acid would also be obvious to one with ordinary skill in the art. Again, the specification

for the current application does not demonstrate the criticality, rather states that it is in one embodiment.

8. Claims 35-39 rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et al. in US Patent No. 5,879,713 in view of Boock et al. in US Patent No. 6,187,024. Roth discloses the invention with the exception of:

- An implant that is a hybrid bioactive coil.
- A hybrid bioactive coil that is a composite of the biocompatible and bioabsorbable polymer and an inert biocompatible coil.
- An inert biocompatible coil that is a platinum coil.
- A composite of the biocompatible and bioabsorbable polymer and an inert biocompatible coil that is a layer of the biocompatible and bioabsorbable polymer on the inert biocompatible coil.
- A composite of the biocompatible and bioabsorbable polymer and an inert biocompatible coil that is threads of the biocompatible and bioabsorbable polymer attached to the inert biocompatible coil.

On the other hand, Book et al. teach a coil with a coating. Therefore, it would be obvious to one with ordinary skill in the art to use the coating as taught by Roth et al. on a coil as taught by Boock et al. for the purpose of promoting better healing. Further, it would be obvious to one with ordinary skill in the art to provide a hybrid bioactive coil that is a composite of the biocompatible and bioabsorbable polymer and an inert biocompatible coil, where the inert biocompatible coil that is a platinum coil for the purpose of enchased healing.

Moreover, a composite of the biocompatible and bioabsorbable polymer and an inert biocompatible coil that that is a layer of the biocompatible and bioabsorbable polymer on the inert biocompatible coil and a composite of the biocompatible and bioabsorbable polymer and an inert biocompatible coil that that is threads of the biocompatible and bioabsorbable polymer attached to the inert biocompatible coil would also be obvious to one with ordinary skill in the art.

Double Patenting

9. Claims 1-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,423,085. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps a bit more broad in some aspects while a bit more narrow in others.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2002/0168398; US Patent No. 6,585,754; US Patent No. 6,569,179; US Patent No. 6,530,951; US Patent No. 6,280,457; US Patent No. 6,261,587; US Patent No. 6,231,881; US Patent No. 5,788,979; US Patent No. 5,626,863; US Patent No. 5,324,647; and GB 2 215 209.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700